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The use of nanofood in foodstuff final products for humans and animals

The present invention relates to the use of nanofood in foodstuff final products, to foodstuff final products containing this nanofood as well as to the various applications of these foodstuff final products for humans and animals.

) Foodstuff final products within the context of the present invention are drinks, foodstuffs, diet foodstuffs, energy drinks, energy food and functional food. Functional food is every modified foodstuff or constituents thereof which additionally to their natural form have a preventative or health use as well as stimulate or improve body functions. Synonymous terms for functional food are pharmafood, medical food or designer food.

) It is the object of the present invention to stably work slightly water soluble and water insoluble nutrients and nutraceuticals into foodstuff final products. Nutraceuticals are natural and synthetic substances which have a preventative or health use as well as stimulate or improve body functions.

For achieving this object there are essentially available the following two methods: microencapsulating solid substances and oils and emulsifying oils or solid substances, where appropriate micronised, suspended in oils. These manufacturing processes are very expensive and difficultly controllable. Such microencapsulated or emulsified nutrients and nutraceuticals worked into the final products may sediment and cream which has as a consequence an undesired reduction in quality. Both phenomena could be reduced or prevented if it were possible to manufacture ultra-small, homogeneous, nutrient-loaded or nutraceutical-loaded

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particles which, suspended or emulsified in water or in the aqueous phase of the final product, no longer aggregate.

It has been surprisingly ascertained that with so-called nanofood, containing

- (a) a membrane-forming molecule
- (b) a co-emulsifier
-) (c) a lipophilic component

water insoluble or slightly water soluble nutrients and nutraceuticals may be added into foodstuff final products so that their stability is ensured.

The subject-matter of the present invention it therefore the use of a nanofood containing as a preparative composition

- (a) a membrane-forming molecule
- (b) a co-emulsifier
-) (c) a lipophilic component

in foodstuff final products.

Preferably the nanofood contains

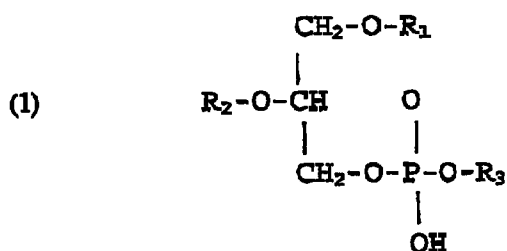
- (a) as membrane-forming molecules, substances which are suitable for forming two-layer systems (so-called bilayers),
- (b) as co-emulsifiers, substances which preferably form O/W structures and
- (c) as lipophilic components, a usual lipophilic nutrient or a usual lipophilic nutraceutical.

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Preferably the nanofood contains as component (a) a phospholipid, a hydrated or partly hydrated phospholipid, a lysophospholipid or mixtures from these compounds.

Very particularly preferred with this is a phospholipid of the formula:



wherein

R₁ means C₁₀-C₂₀-acyl;

R₂ hydrogen or C₁₀-C₂₀-acyl;

R₃ hydrogen, 2-trimethylamino-1-ethyl, 2-amino-1-ethyl, C₁-C₅-alkyl which is non-substituted or substituted by one or more carboxy groups, hydroxy groups or amino groups; which means inositol or glyceryl groups, or salts of these compounds.

C₁₀-C₂₀-acyl is preferably a straight-chained C₁₀-C₂₀-alkanoyl with an even number of C-atoms and straight-chained C₁₀-C₂₀-alkenoyl with one or more double bonds and an even number of C-atoms.

Straight-chained C₁₀-C₂₀-alkanoyl with an even number of C-atoms are for example n-dodecanoyl, n-tetradecanoyl, n-hexadecanoyl or n-octadecanoyl.

Straight-chained C₁₀-C₂₀-alkenoyl with one or more double bonds and an even number of C-atoms are for example 6-cis- or -6-trans-, 9-cis- or 9-trans- dodecenoyl, -tetradecanoyl, - hexadecenoyl, -

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octadecenoyl or -icosenoyl, in particular 9-cis-octa-decenoyl (oleoyl), further 9, 12-cis-octadecadienoyl or 9,12,15-cis-octadecatrienoyl.

A phospholipid of the formula (1), wherein R_3 means 2-trimethylamino-1-ethyl, is indicated with by trivial name lecithin and a phospholipid of the formula (1), wherein R_3 means 2-amino-1-ethyl, is indicated by the trivial name kephalin. Suitable are for example naturally occurring kephalin or lecithin, e.g. kephalin or lecithin from soya beans or hens eggs with different or identical acyl groups or mixtures.

The phospholipid of the formula (1) may however also be of a synthetic origin. Under the term synthetic phospholipid one defines phospholipids which with respect to R_1 and R_2 have a uniform composition. Such synthetic phospholipids are preferably the lecithins and kephalins described later, whose acyl groups R_1 and R_2 have a defined structure and are derived from a defined fatty acid with a degree of purity higher than approx. 95%. R_1 and R_2 may be equal or different and unsaturated or saturated. Preferably R_1 is saturated, e.g. n-hexadecanoyl, and R_2 unsaturated, e.g. 9-cis-octadecenoyl (oleoyl).

The term "naturally occurring" phospholipid of the formula (1) defines a degree of purity of more than 90% by weight, preferably more than 95% by weight of the phospholipid of the formula (1), which is able to be proven by way of suitable detecting methods, e.g. paper-chromatographically or thin-layer chromatographically, with the HPLC or enzymatic colour test.

In a phospholipid of the formula (1) R_3 means C_1 - C_4 -alkyl, for example methyl or ethyl. The meaning methyl is preferred.

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R₃ with the meanings C₁-C₅-alkyl substituted by one or more carboxy groups, hydroxy groups or amino groups are for example 2-hydroxyethyl, 2,3-dihydroxy-n-propyl, carboxymethyl, 1 or 2 carboxyethyl, dicarboxymethyl, 2-carboxy-2-hydroxyethyl or 3-carboxy-2,3-dihydroxy-n-propyl or 2-amino-2-carboxy-n-propyl, preferably 2-amino-2-carboxyethyl.

Phospholipids of the formula (1) with these groups may be present in salt form, e.g. as sodium or potassium salt.

Phospholipids of the formula (1), wherein R₃ means the inositol or the glyceryl group, are known under the descriptions phosphatidylinositol and phosphatidylglycerol.

For the acyl residue in the phospholipids of the formula (1) the descriptions indicated in brackets are also usual:

9-cis-dodecenoyl (lauroleoyl), 9-cis-tetradecenoyl (myristoleoyl), 9-cis-hexadecenoyl (palmitoleoyl), 6-cis-octadecenoyl (petroseloyl), 6-trans-octadecenoyl (petroselaidoyl), 9,12-cis-octadecenoyl (oleoyl), 9-trans-octadecenoyl (elaidoyl), 9,12-cis-octadecadienoyl (linoleoyl), 9,12,15-cis-octadecatrienoyl (linolenoyl), 11-cis-octadecenoyl (vaccenoyl), 9-cis-icosenoyl (gadoleoyl), 5,8,11,14-cis-eicosatetraenoyl (arachidonoyl), n-hexadecanoyl (palmitoyl), n-octadecanoyl (stearoyl), n-icosanoyl (arachidoyl), n-docosanoyl (behenoyl), n-tetracosanoyl (lignoceroyl).

A salt of the phospholipids of the formula (1) is acceptable. Salts are defined by the existence of salt-forming groups in the substituent R₃ as well as by the free hydroxy group of phosphorus. Possible is likewise the formation of inner salts. Preferred are free alkali metal salts, in particular sodium salts.

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In a particularly preferred embodiment form one uses purified lecithin from soja beans of the quality LIPOID S 100 or S 75 or a lecithin defined in the monography of the USP23 / NF 18.

The component (a) is preferably applied in a concentration of approx. 0.1 to 30% by weight with respect to the total weight of the components (a), (b), and (c).

) The nanofood containing

- (a) as a membrane-forming molecule a phospholipid,
- (b) a co-emulsifier and
- (c) a lipophilic component

represents a further subject-matter of the invention.

As component (b) preferably an emulsifier of emulsifier mixture is/are used, which preferably forms/form O/W structures.

) Specially preferred emulsifiers are:

- alkali salts, ammonium salts and amine salts of fatty acids. Examples for such salts are lithium salts, sodium salts, potassium salts, ammonium salts, triethylamine salts, ethanolamine salts, diethanolamine salts or triethanolamine salts. In particular the sodium salts, potassium salts or ammonium ($NR_1R_2R_3$) salts are used, wherein R_1 , R_2 , R_3 independently of one another mean hydrogen, C_1 - C_4 -alkyl or C_1 - C_4 -hydroxyalkyl;
- alkyl sulphates such as e.g. sodium docecylsulphate;
- salts of the bile acids such as e.g. sodium cholate, sodium glyocholate and sodium taurocholate;

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- partial fatty acid esters of sorbitane such as e.g. sorbitane monolaurate
- sugar esters such as e.g. sucrose monolaurate;
- fatty acid partial glycerides such as e.g. lauric acid monoglyceride;
- polyglycerine esters of fatty acids;
- propylene glycol esters of fatty acids;
- lactic acid esters of fatty acid such as e.g. sodium stearoyl-lactyl-2-lactate;
- proteins such as e.g. casein.

Emulsifiers of the polyoxyethylene type are very particularly preferred. Examples of such emulsifiers are

- polyethoxylised sorbitane fatty acid ester such as e.g. polysorbate 80;
- polyethoxylised vitamin E derivatives such as e.g. vitamin E polyethylene glycol 1000 succinate;
- polyethoxylised fatty acid esters such as e.g. polyoxyl(20) stearate;
- polyoxyethyleneglycolised natural or hydrated vegetable oils such as e.g. polyoxyethylene-glycolised natural or hydrated castor oils;
- polyethoxylised fatty acid partial glycerides such as e.g. diethyleneglycol monostearate;
- polyethoxylised carbohydrates;
- blockcopolymerisates of ethylene oxide and propylene oxide, such as e.g. Poloxamer 188.

The component (b) is present in the nanofood used according to the invention in a concentration of approx. 1 to approx. 50% by weight with respect to the total weight of the components (a), (b) and (c).

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The nanofood containing

- (a) a membrane-forming molecule,
 - (b) as a co-emulsifier an emulsifier of the polyoxyethylene type and
 - (c) a lipophilic component
- represents a further subject-matter of the invention.

-) The component (c) is preferably a natural, a synthetic or a partial synthetic diglyceride or triglyceride, a fat, a water insoluble, a slightly water soluble, an oily or an oil-soluble nutrient respectively nutraceutical or mixtures of these substances.

Nutrients suitable for the application according to the invention are fats, proteins, carbohydrates, salts, vitamins and trace constituents.

-) Nutraceuticals suitable for the application according to the invention are for example vitamins, antioxidants, phytochemicals and zoochemicals.

Examples of vitamins and antioxidants are vitamin E and derivatives, tocotrienols, vitamin A and derivatives, vitamin C, beta-carotene, carotinoids, flavonoids, lycopene, luteins and lipon acids.

Examples of phytochemicals, i.e. natural components of plants, are oils and essential oils such as e.g. wheat [germ] oil, maize [germ] oil, thistle oil, linseed oil, rose hip [germ] oil, hemp oil, hazlenut oil, halibut liver oil, red/blackcurrent seed oil, caraway oil, pumpkin seed oil, olive oil, peanut oil, rape oil, soja oil, sesame oil, apricot and peach core oil, cotton seed oil,

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cherry seed oil, pistachio oil, evening primrose oil, borragé oil, rice [germ] oil, mustard seed oil, sunflower oil, grape seed oil, peppermint oil, melissa oil, citronella oil, lemon grass oil, lemon oil, sage oil, oily thyme extracts, rosemary extracts, orange blossom oil, pine-free juniper oil, camilla oil and extracts, yarrow blossom oil, cinammon oil, corriander oil, aniseed oil, and fennel oil.

) Spicy substances, bitter substances, spices, tanning substances and saponines are further examples of phytochemicals.

Examples of zoochemicals, i.e. natural components of animal tissue are liver train, fish oil, salmon oil, salmon oil ethylester concentrate and fish oil ethylester concentrate.

) Further examples of nutraceuticals are unsaturated omega-9-fatty acids such as e.g. oleic acid, omega-6-fatty acids such as e.g. linoleic acid, gamma-linolenic acid acid, dihommo-gamma linolenic acid and arachidonic acid and omega-3-fatty acids such as alpha linolenic acid, stearidonic acid, eicosapentaenoic acid and docosahexanoic acid.

Likewise examples of nutraceuticals are amino acids, ubiquiones such as coenzyme Q10, carnitine, creatine, dithiolethione (oltipraz), tamoxifene, resveratrole and taurine.

The component (c) is present in the nanonfood use according to the invention in a preferred concentration of 0.1 to 70% by weight with respect to the total weight of the components (a), (b) and (c).

The nanofood containing

a) a membrane-forming molecule

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- b) a co-emulsifier and
- c) as a lipophilic component a fat-soluble vitamin, a carotinoide, a flavonoide, a ubiquinone, a vegetable or animal oil, an essential oil, an omega-9 fatty acid, an omega-6 fatty acid, an omega-3 fatty acid or mixtures of these substances represents a further subject-matter of the invention.

) Where appropriate the nanofood applied according to the invention contains as an optional component (d) a solutiser, preferably a C₂-C₅ alcohol such as e.g. ethanol or propylene glycol.

) A nanofood composition with the components (a), (b) and (c) is distinguished with the dispersion in an aqueous medium by favourable phase properties. Thus with a present opalescence and transparency in counterlight it can only be recognised with an extremely slight milky cloudiness that the dispersion still has physical differences with respect to the ideal condition of a purely molecular solution. Electron microscope imagings show that a population of more than 98% in a normal distribution is present as a suspension of particles with a particle size smaller than approx. 80 nm, typically smaller than approx. 40 nm. These differences with respect to a pure solution however on account of the particularly good homogeneity properties of the dispersion may be tolerated, which for example may be shown by a surprisingly high storage stability, i.e. no demixing after a storage for several months at temperatures up to room temperature (by extrapolation, the stability to be expected is longer than two years).

For manufacturing the nanofood the two components (b) and (c) are mixed to a homogeneous fluid phase, where appropriate with amid heating. In this phase the component (a) is dissolved, where

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) appropriate with the help of a solubiliser such as ethanol. From this there results a clear liquid, the so-called nanofood prephase. This is added amid stirring to the aqueous phase, where appropriate containing water soluble nutrients or nutraceuticals. The stirring is effected with usual stirring apparatus, such as e.g. propeller stirring devices, slant-blade stirring devices or magnet stirring devices. By way of the particular selection of the components (a), (b) and (c) there arise at the same time direct ultra-fine, mono-dispersed nano foods. With this one may do away with a homogenisation by way of nozzle homogenisers, rotor-stator homogenisers or ultrasound homogenisers, which produce high shear forces and cavitation forces.

The addition of the nanofood prephase to the aqueous phase is usually carried out at room temperature which lies in the region of the respective oil/water phase inversion temperature (PIT).

) The nanofoods characterised by the described manufacturing method have an average particle diameter of smaller than 80 nm, typically smaller than 40 nm. The particle distribution is mono-dispersed and obeys a normal distribution. Laser light scattering measurements and electron microscope examinations (Cryo-TEM) confirm the very small size and excellent homogeneity of the nanofoods.

The nanofood composition according to the invention is used for foodstuff final products.

Preferably the foodstuff final products are liquid, semi-solid or solid.

Liquid foodstuff final products are e.g. still and carbon-dioxide containing mineral water, aromatised water, fruit juices, classic-

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fruit juices or syrups, vegetable juices and syrups, milk, milk imitation products and sauces.

Examples of semi-solid foodstuff final products are yoghurt, cream cheese, margarine, high-fat containing emulsions, spreads and ice-cream.

Solid foodstuff final products are e.g. instant products, chocolate, bread and biscuits, fish and sausage products, pasta and potato products.

These foodstuff final products containing nanofood form a further subject-matter of the invention.

The foodstuff final products with this contain the nanofood in a concentration of 0.01 to 100% by weight.

For manufacturing fluid (Examples 11-16) and semi-solid (Example 17) foodstuff final products the nanofoods are worked into the aqueous part of the final product. The working-in of the nanofoods is effected preferably amid stirring at room temperature, wherein usual stirring apparatus are applied such as e.g. propeller stirring devices, slant-blade stirring devices or magnet stirring devices.

Instead of the nanofoods also the corresponding nanofood- prephase may be worked into the aqueous part of the final formulation. The addition of the nanofood prephase into the aqueous part of the final products is effected amid stirring and preferably at a temperature which lies in the region of the reseptive oil/water inversion temperature (PIT).

for diseases with humans and animals.

In the following examples the percentages are related to weight. With the used compounds the quantities, insomuch as not specified

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Incr Omega E3322 (Croda)	5.50%	
vitamin E acetate	0.63%	
soya lecithin	0.30%	
Polysorbate 80	3.50%	
ethanol	0.10%	
10mM phosphate buffer, pH 6	ad	100.00%

coenzyme Q10 amid stirring and heating. From this there resulted a clear fluid which amid stirring (e.g. a magnet stirring device) is added to the water phase which was previously heated to 50°C.

In the subsequent Table 1 the particle sizes of the nanofoods are drawn up.

¹ The particle diameter and the particle size distributions were determined by way of laser light scattering (Nicom 370 Submicron Particle Sizer, Number weighting)

² The particle diameter and the particle size distributions were determined by way of laser light scattering (Nicom 370 Submicron Particle Sizer, Number weighting)

³ The content of vitamin E acetate was determined by way of HPLC

glucose	7.5%
aroma	0.1%
nanofood according to Example 6	0.2%
water	ad 100.00%

⁴ The particle diameter and the particle size distributions were determined by way of laser light scattering (Nicom 370 Submicron Particle Sizer, Number weighting)

⁵ The content of vitamin E acetate was determined by way of HPLC

nanofood according to Example 6	0.2%
milk	ad 100.00%

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Example 16: ACE drink

vitamin C	0.06%
nanofood according to Example 6	0.20%
nanofood according to Example 7	0.17%
orange juice	ad 100.00%

Example 17: omega-3 yoghurt

nanofood according to Example 8	3.0%
orange juice	ad 100.0%

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**Patent claims**

1. The use of a nanofood containing as a preparative composition
 - (a) a membrane-forming molecule
 - (b) a co-emulsifier
 - (c) a lipophilic componentin foodstuff final products.
2. The use according to claim 1, characterised in that the nanofood contains
 - (a) as membrane-forming molecules, substances which are suitable for forming two-layer systems,
 - (b) as co-emulsifiers, substances which preferably form O/W structures and
 - (c) as a lipophilic component, a usual lipophilic nutrient or a usual lipophilic nutraceutical.
3. The use according to claim 1 or 2, characterised in that the nanofood contains as component
 - (a) a phospholipid, a hydrated or partly hydrated phospholipid, a lysophospholipid or mixtures of these.
4. The use according to one of claims 1 to 3, characterised in that the component (a) is present in the nanofood used according to the invention, in a concentration of 0.1 to 30% by weight with respect to the total weight of the components (a), (b) and (c).
5. The use according to one of claims 1 to 4, characterised in that the nanofood as component
 - (b) contains alkali metal salts, ammonium salts or amine salts, of fatty acids, alkyl sulphates, salts of the bile acids, partial fatty acid esters of sorbitane,



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sugar esters, fatty acid partial glycerides, polyglycerine esters of fatty acids, propylene glycol esters of fatty acids, lactic acid esters of fatty acids, proteins, emulsifiers of the polyoxyethylene type or mixtures of these substances.

6. The use according to claim 5, characterised in that the nanofood as component
(b) contains an emulsifier of the polyoxyethylene type.
7. The use according to claim 6, characterised in that the nanofood as component
(b) contains polyethoxylised sorbitane fatty acid ester, polyethoxylised vitamin E derivatives, polyethoxylised fatty acid esters, polyoxyethylene-glycolised natural or hydrated vegetable oils, polyethoxylised fatty acid partial glycerides, polyethoxylised carbohydrates; blockcopolymerisates of ethylene oxide and propylene oxide or mixtures of these substances.
8. The use according to one of claims 1 to 7, characterised in that the component (b) is present in the nanofood used according to the invention in a concentration of approx. 1 to approx. 50% by weight with respect to the total weight of the components (a), (b) and (c).

The use according to one of the claims 1 to 8, characterised in that the nanofood as component

- (c) contains a natural, a synthetic or a partial synthetic diglyceride or triglyceride, a fat, a water insoluble, a slightly water soluble, an oily or an oil-soluble nutrient respectively nutraceutical or mixtures of these



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substances.

The use according to claim 9, characterised in that the nanofood as component

(c) contains a fat-soluble vitamin, a carotinoide, a flavonoide, a ubiquinone, a vegetable or animal oil, an essential oil, an omega-9 fatty acid, an omega-6 fatty acid or an omega-3 fatty acid or mixtures of these substances.

11. The use according to one of claims 1 to 10, characterised in that the component (c) is present in the nanofood used according to the invention in a concentration of 0.1 to 70% by weight with respect to the total weight of the components (a), (b) and (c).
12. The use according to one of claims 1 to 11, characterised in that the nanofood additionally as component (d) contains a C₂-C₅ alcohol.
13. The use according to one of the claims 1 to 12, characterised in that the foodstuff final product is liquid, semi-solid or solid.
14. A liquid foodstuff final product in the form of a mineral water, of a fruit juice, of a classic-fruit juice, of a vegetable juice, of a sirup, of a milk, of a milk imitation product, containing a nanoprodukt as defined in claim 1.
15. A semi-solid foodstuff final product in the form of a yoghurt, a cream cheese, a margarine, a high-fat-containing emulsion, a spread, an ice-cream, a mineral water, containing a nanofood as defined in claim 1.



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16. A solid foodstuff final product in the form of an instant powder, of a powder, of a granulate, of a lyophilisate, containing a nanofood as defined in claim 1.
17. A foodstuff final product, characterised in that the nanofood is present in its aqueous phase.
18. A foodstuff final product according to claim 16, characterised in that the nanofood is present in a dehydrated form.
19. A foodstuff final product according to one of claims 14 to 18, characterised in that the foodstuff final product contains the nanofood in a concentration of 0.01 to 100% by weight.
20. A method for manufacturing a liquid or semi-solid foodstuff final product according to claim 14 and 15, characterised in that the nanofood is worked into the aqueous part of the final product.
21. A method for manufacturing a solid foodstuff final product according to claim 16, characterised in that the foodstuff final product is coated or loaded with the nanofood.
22. A method for manufacturing a solid foodstuff final product according to claim 16, characterised in that the nanofood in dehydrated form is admixed to the solid substance mixture.
23. The use of the foodstuff final product according to one of the claims 13 to 19 for nutrition, for dietary nutrition, for stimulating and improving body functions, for prevention, for



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supporting therapy or for the therapy of diseases with humans and animals.

24. The use of a foodstuff final product according to one of claims 13 to 19 as a drink, as a foodstuff, as a feed, as a diet foodstuff, as an energy drink, as energy food or as functional food.

25. A nanofood containing as a preparative composition

- (a) a membrane-forming molecule
- (b) a co-emulsifier
- (c) a lipophilic component

in foodstuff final products.

26. A nanofood according to claim 25, characterised in that the nanofoods as component

- (a) contains a phospholipid, a hydrated or partly hydrated phospholipid, a lysophospholipid or mixtures of these substances.

27. A nanofood according to one of the claims 25 or 26, characterised in that the nanofood as component

- (b) contains an emulsifier of the polyoxyethylene type.

A nanofood according to one of the claims 25 to 27, characterised in that the nanofood as component

- (c) contains a fat-soluble vitamin, a carotinoide, a flavonoide, a ubiquinone, a vegetable or animal oil, an essential oil, an omega-9 fatty acid, an omega-6 fatty acid or an omega-3 fatty acid.

(β) addition of the fluid obtained in step (α) into an aqueous phase, characterised in that steps (α) and (β) are effected without further energy expense.



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33. A nanofood according to claim 32, characterised in that the step (β) is effected without homogenising.
34. A nanofood according to one of the claims 32 or 33, characterised in that the nanofood has an average particle size of smaller than 80 nm.

